Medsenic Announces Positive Results of its Phase II Clinical Study with Arscimed® for the Treatment of Chronic Graft Versus Host Disease (cGvHD)

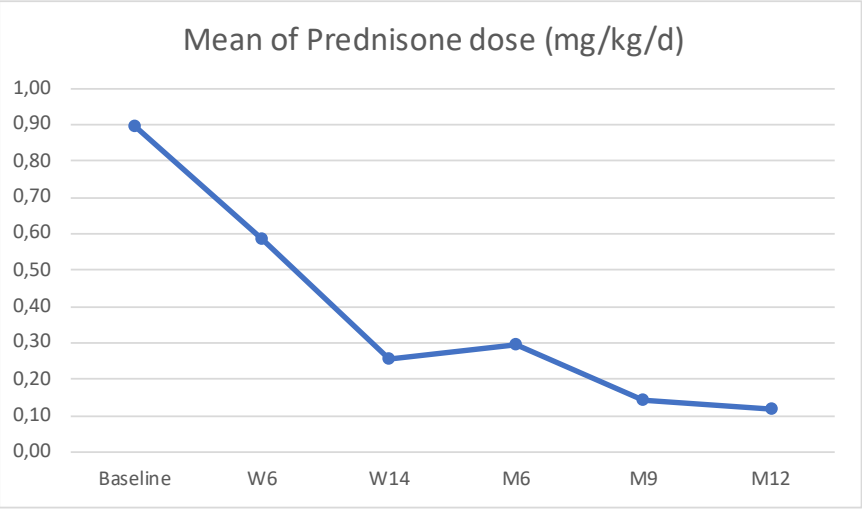
- *Arscimed® (arsenic trioxide) reaches an impressive 75% clinical efficacy at 6 months when administered intraveinously over one month to moderate to severe cGvHD patients*
- *Primary efficacy endpoint met: complete or partial disease remission at 6 months and sustained response at 12 months*
- *Very significant reduction in corticosteroid use*

Strasbourg, France, March 29th 2021 – Medsenic, a clinical stage biopharmaceutical company focusing on the discovery and development of new indications and formulations of arsenic salts for the treatment of severe autoimmune diseases, announced today the positive results of its Phase II clinical study GMED-16-001 with its lead product Arscimed®, an intravenous formulation of arsenic trioxide, in patients with Chronic Graft Versus Host Disease (GvHD).

"These excellent results are a significant step forward for the management of patients with cGvHD, a rare, complex and extremely debilitating autoimmune disease affecting over 40,000 people worldwide and for which there is no satisfactory treatment. The study data validate the therapeutic potential of our product Arscimed®, as a new selective immunosuppressive/anti-inflammatory drug for cGvHD. We look forward to confirming its efficacy in a Phase III study as well as its significant impact on improving the quality of life of GvHD patients," said Prof. **François Rieger, President and co-founder of Medsenic**.

The primary endpoint of the prospective Phase II multicentre, non-randomised GMED-16-001 study was the improvement of treatment response, i.e., **complete or partial disease remission 6 months after GvHD diagnosis**, with Arscimed® in combination with prednisone with or without cyclosporine.

Over a 4-week period, 21 patients with moderate to severe chronic GvHD received as first-line treatment daily intravenous infusions of Medsenic's arsenic trioxide drug. The first improvements were observed 6 weeks after the infusion. The reduction of the initial dose of 1 mg prednisone/kg/day (standard care with or without cyclosporine) can be started at this stage, with a view to discontinue corticosteroids once complete remission has been achieved. **This ability to eliminate the use of corticosteroids is a major advantage of arsenic trioxide treatment**.



After the 6-month follow-up, the study's primary endpoint was met in 15 of 21 patients, with a **75% clinical efficacy rate** (95% exact CI: [50.9%; 91.3%]). **This very encouraging result was confirmed by a sustained response at 12 months post-treatment in all patients.**

About Arscimed®

The active pharmaceutical ingredient (API) of Arscimed® is arsenic trioxide. Medsenic has harnessed its expertise to develop and manufacture a formulation of arsenic trioxide for IV injection. Arsenic trioxide belongs to a new class of drugs able to radically modify the autoimmune cascade and normalise the immune system without causing nonspecific immunosuppression.

The main action of arsenic trioxide is the activation of a strong oxidative stress-induced pathway in activated immune cells, and the elimination of certain subtypes of pathogenic immune cells eliciting autoimmune reactions. It also suppresses abnormal biological processes associated with immune disorders, such as the excessive production of proinflammatory cytokines.

About cGvHD

cGvHD - Chronic Graft versus Host Disease - is a complex autoimmune reaction that develops following bone marrow transplants or, more precisely, allogeneic hematopoietic stem cells, with a frequency of 30-60 % of the treated patients. It affects each year approximately 16,000 people in the European Union and 20,000 in the United States and Canada, which places it under the classification of Orphan Disease.

After grafting, the donor immunocompetent cells often trigger an immune response against the recipient - called the "Host". They will recognize the recipient's own antigens as foreign and will seek to destroy them. The donor's T cells thus attack the host's tissues and organs. This phenomenon can even be observed between donor and host who are very close immunologically. This disease remains a major obstacle to therapeutic transplants in hemato-oncology... A so-called acute GvHD occurs in the weeks following transplantation. After a certain period of time, the reaction changes in nature and displays autoimmune disease characteristics. It becomes chronic, with a continuous aggravation, often uncontrolled by conventional immunosuppressive treatments, and has a poor prognosis, making cGvHD potentially fatal. This is why there is an urgent need for new therapeutic approaches.

About Medsenic

Medsenic is innovating and exploiting the new possibilities offered by the therapeutic use of arsenic trioxide in several autoimmune diseases and is currently in the process of clinical studies in Europe.
The company was created in 2010 by Prof. François Rieger, former Research Director CNRS, author of more than 170 international scientific publications, and Véronique Pomi-Schneiter, former founder and manager of a consulting company in human resources, communication and development strategies. Under the aegis of a high-level scientific council, chaired by the 2011 Nobel Prize for Medicine Jules Hoffmann, a specialist in Innate Immunology, and supported by a solid core of private investors, Medsenic accelerated its development in 2016 with the financial support of institutionnal investors, Cap Innov'Est, Fa Dièse and CNRS Innovation SA.

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